AMENDED IN ASSEMBLY APRIL 7, 1997

CALIFORNIA LEGISLATURE—1997–98 REGULAR SESSION

# ASSEMBLY BILL No. 764

**Introduced by Assembly Member Davis**

February 26, 1997

~~An act to add Section 100197 to the Health and Safety Code,~~ *An act to amend Sections 110403, 111635, and 111655 of, and to repeal Section 110305 of, the Health and Safety Code,* relating to food and drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 764, as amended, Davis. Food and drug inspections.

Existing law requires the State Department of Health Services to cause a special investigation of the preparation and sale of drugs and food and their adulteration. Existing law also requires the department to perform duties that are required by law for the detection and prevention of the adulteration of articles used for food and drink, and for the punishment of persons who are found guilty of violating any law providing against their adulteration.

~~This bill would require the Legislative Analyst to conduct a study that examines the regulation of pharmaceuticals, biologic products, medical devices, and in vitro diagnosis by the food and drug branch of the department and report to the Legislature on or before January 1, 1999.~~

*Existing law provides that it is unlawful for any person to use on the labeling of any drug or device, or any advertisement relating to any drug or device, any representation or*

*suggestion that an application is effective under a prescribed provision of law relating to new drugs and devices or that the drug or device complies with that law.*

*This bill would repeal that provision.*

*Existing law provides that it is unlawful for any person to advertise any drug or device represented to have any effect in enumerated conditions, disorders, or diseases.*

*This bill would create an exception to that provision if the advertisement is in compliance with prescribed federal law.*

*Existing law requires the department to inspect each place of business for the manufacture of any drug or device prior to issuing or renewing an annual license.*

*This bill would instead require the department to make that inspection once every 2 years.*

*Existing law prohibits any person from manufacturing any drug or device without a license from the department and exempts from that licensure requirement certain entities.*

*This bill would also exempt from licensure any person who has registered an establishment and listed all products in compliance with a prescribed federal law and submits a copy of the federal registration and listing to the department in accordance with regulations established by the department.*

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~ *yes*. State-mandated local program: no.

*The people of the State of California do enact as follows:*

~~SECTION 1. Section 100197 is added to the Health~~

*SECTION 1. The Legislature finds and declares all of the following:*

*(a) The medical technology industry, encompassing biotechnology and medical device and equipment manufacturing, is a rapidly growing California industry, and is critical to the future health of California's economy.*

*(b) This industry produces therapeutic drugs, medical devices, equipment, and diagnostic products transforming the practice of medicine and improving the lives of millions of patients around the world.*

*(c) The majority of the companies comprising this sector are small businesses who must invest heavily in*

*research and development for several years before they market their first product, and who are heavily impacted by federal and state regulation.*

*(d) The businesses that comprise this industry are subject to rigorous health and safety regulation by the U.S. Food and Drug Administration (FDA), which maintains primary jurisdiction over this industry.*

*(e) The Legislature should, to the extent possible, seek to reasonably reform state laws and regulations that duplicate federal laws and regulations with respect to this industry, with the goal being to eliminate duplicative procedures which add no value to consumers.*

*SEC. 2. Section 110305 of the Health and Safety Code is repealed.*

~~110305. It is unlawful for any person to use on the labeling of any drug or device, or any advertisement relating to any drug or device, any representation or suggestion that an application with respect to the drug or device is effective under Section 111550 or that the drug or device complies with that section.~~

*SEC. 3. Section 110403 of the Health and Safety Code is amended to read:*

110403. It is unlawful for any person to advertise any drug or device, *except in compliance with subdivisions (n) and (r) of Section 352 of Title 21 of the United States Code,* represented to have any effect in any of the following conditions, disorders, or diseases:

(a) Appendicitis.
(b) Blood disorders.
(c) Bone or joint diseases.
(d) Kidney disease or disorders.
(e) Cancer.
(f) Carbuncles.
(g) Disease, disorder, or condition of the eye.
(h) Diabetes.
(i) Diphtheria.
(j) Gall bladder disease or disorder.
(k) Heart and vascular diseases.
(*l*) High blood pressure.

(m) Diseases or disorders of the ear or auditory apparatus, including hearing loss and deafness.
(n) Measles.
(o) Meningitis.
(p) Mental disease or mental retardation.
(q) Paralysis.
(r) Pneumonia.
(s) Poliomyelitis.
(t) Prostate gland disorders.
(u) Conditions of the scalp, affecting hair loss, or baldness.
(v) Alcoholism.
(w) Periodontal diseases.
(x) Epilepsy.
(y) Goiter.
(z) Endocrine disorders.
(aa) Sexual impotence.
(ab) Sinus infection.
(ac) Encephalitis.
(ad) Tumors.
(ae) Venereal disease.
(af) Tuberculosis.
(ag) Ulcers of the stomach.
(ah) Varicose ulcers.
(ai) Scarlet fever.
(aj) Typhoid fever.
(ak) Whooping cough.
(a*l*) Acquired immune deficiency syndrome (AIDS).
(am) AIDS-related complex (ARC).
(an) Diseases, disorders, or conditions of the immune system.

*SEC. 4. Section 111635 of the Health and Safety Code is amended to read:*

111635. ~~Prior to issuing or renewing a license required by Section 111615, the~~ *The* department shall inspect each place of business *once every two years* to determine ownership, adequacy of facilities, and personnel qualifications.

*SEC. 5. Section 111655 of the Health and Safety Code is amended to read:*

111655. The licensing provisions of this chapter shall not apply to any of the following:

(a) Any pharmacy that maintains establishments in conformance with provisions of the Pharmacy Law, Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code, regulating the practice of pharmacy, and that is regularly engaged in dispensing prescription drugs or devices, upon prescriptions of any person licensed to administer the drugs or devices to patients under the care of the person in the course of his or her professional practice, and that does not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of his or her business of dispensing or selling drugs or devices at retail.

(b) Any pharmacy that solely engages in providing drugs or devices to a person licensed by law to administer the drug or device for his or her use in the course of his or her professional practice.

(c) Any pharmacy that solely provides drugs or devices to another pharmacy in order to meet a temporary inventory shortage.

(d) Any person who is licensed by law to prescribe or administer drugs or devices and who manufactures, prepares, propagates, compounds, or processes drugs or devices solely for use in the course of his or her professional practice.

(e) Any person who manufactures, prepares, propagates, compounds, or processes any drug or device solely for use in nonclinical research, teaching, or chemical analysis and not for sale.

(f) Any wholesaler, as defined in Section 4038 of the Business and Professions Code.

(g) Any such other class of persons as the department may by regulation exempt from the application of this article upon a finding that licensing by a class of persons in accordance with this article is not necessary for the protection of the public health.

(h) Any registered dispensing optician licensed pursuant to the provisions of Chapter 5.5 (commencing

with Section 2550) of Division 2 of the Business and Professions Code, who is regularly engaged in dispensing or selling prescription lenses and frames, and not engaged in the manufacture, preparation, processing or assembling of lenses or frames for sale other than in the regular course of his or her business of dispensing or selling lenses or frames at retail.

*(i) Any person who has registered an establishment and listed all products in compliance with Section 360 of Title 21 of the United States Code and submits a copy of the federal registration and listing to the department in accordance with regulations established by the department.*

~~and Safety Code, to read:~~

~~100197. The Legislative Analyst shall conduct a study that examines the regulation of pharmaceuticals, biologic products, medical devices, and in vitro diagnosis by the food and drug branch of the State Department of Health Services under applicable provisions of this code. The Legislative Analyst shall report the results of the study to the Legislature on or before January 1, 1999. The report shall include the following:~~

~~(a) The scope of regulation by the food and drug branch of the department.~~

~~(b) The extent to which the regulatory activities duplicate federal regulation of the affected companies by the United States Food and Drug Administration (FDA) under the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.).~~

~~(c) The extent to which the food and drug branch of the department adequately coordinates its inspections and other regulatory actions with the FDA.~~

~~(d) The impact of regulation on biopharmaceutical manufacturers, medical device manufacturers, and in vitro diagnostic manufacturers in the state.~~

~~(e) Recommendations on whether regulation should be modified to eliminate any duplicative regulation of biomedical companies in the state and on how the food~~

~~and drug branch of the department could better coordinate its activities with the FDA.~~

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